CA	EC	INFORMATION TO BE PROVIDED	
		1	**General**
	X	1.1	Receipt of confirmation of EudraCT number
X	X	1.2	Covering letter
X	X	1.3	Application form
	X	1.4	List of Competent Authorities within the Community to which the application has been submitted and details of decisions
X		1.5	Copy of ethics committee opinion in the MS concerned when available
X	X	1.6	Copy/summary of any scientific advice
X	X	1.7	If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor
		2	**Subject related**
X	X	2.1	Informed consent form (for CA: one single template as supportive documentation)
	X	2.2	Subject information leaflet
	X	2.3	Arrangements for recruitment of subjects
		3	**Protocol related**
X	X	3.1	Clinical trial protocol with all current amendments
	X	3.2	Summary of the protocol in the national language (=section 7 of the EC application form)
	X	3.3	Peer review of trial when available
		3.4	Ethical assessment made by the principal/coordinating investigator, if not given in the application form or protocol
		4	**IMP related**
X	X	4.1	Investigator's brochure
X		4.2	Investigational Medicinal Product Dossier (IMPD)
X		4.3	Simplified IMPD for known products
X	X	4.4	Summary of Product Characteristics (SmPC) (for products with MA in the Community)
		4.5	Outline of all active trials with the same IMP
X		4.6	If IMP manufactured in EU and if **no** marketing authorisation in EU: • Copy of the manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
X		4.7	If IMP **not** manufactured in E.U. and if **no** marketing authorisation in EU: • Certification of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP, or that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality • Certification of GMP status of active biological substance • Copy of the importers manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
X		4.8	Certificate of analysis for test product in exceptional cases : Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected
X		4.9	Viral safety studies when applicable.
		4.10	Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals
X		4.11	TSE Certificate, when applicable
		4.12	Examples of the label in the national language
		5	**Facilities & staff related**
	X	5.1	Facilities for the trial
	X	5.2	CV of the coordinating investigator in the MS concerned (for multicentre trials)
	X	5.3	CV of each investigator responsible for the conduct of a trial in a site in the MS concerned (principal investigator)
	X	5.4	Information about supporting staff
		6	**Finance related**
	X	6.1	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial
	X	6.2	Any insurance or indemnity to cover the liability of the sponsor or investigator
	X	6.3	Compensation to investigators
	X	6.4	Compensation to subjects
	X	6.5	Agreement between the sponsor and the trial site
		6.6	Agreement between the investigators and the trial sites
	X	6.7	Certificate of agreement between sponsor and investigator when not in the protocol
		7	**Additional requirements**
X		7.1	NIMP dossier as set out in Section 2.8 of CT-1
X		7.2	If the clinical trial is part of an agreed PIP (Paediatric Investigation Plan), a copy of the Agency's Decision on the agreement on the PIP, and the opinion of the Paediatric Committee, unless these documents are fully accessible via the internet. In the latter case, the link to this documentation in the cover letter is sufficient (see Section 2.3 of CT-1).